

July 14, 1999

Dear Interested Parties:

In my continued effort to keep you informed of Proposition 65 administrative listing activities, I am posting this summary of events and update on the Office of Environmental Health Hazard Assessment (OEHHA) activities. Because of your interest in our work on Proposition 65, I plan to periodically provide you with an update of our activities.

Introduction

The Safe Drinking Water and Toxic Enforcement Act of 1986, or "Proposition 65," was created through the ballot initiative process. Proposition 65 was passed because the people of California wanted to be informed about exposures to chemicals that cause cancer, birth defects, or other reproductive harm, and because they wanted to protect themselves and the water they drink from such chemicals. Consistent with those intentions, "clear and reasonable warnings" are required for knowing and intentional exposures to chemicals that have been placed on the list of substances "known to the State" to cause cancer or reproductive toxicity. Warnings are not required when exposures are below the threshold amounts established in the Proposition. Proposition 65 places the burden for determining if a warning is required on the person or business responsible for creating the exposure to the chemical. While some products now carry a Proposition 65 warning, many businesses have instead prevented exposure to listed chemicals by substitution of less toxic alternatives, or by modifying practices to reduce or avoid public exposure. The Proposition also prohibits discharges of listed chemicals to sources of drinking water unless the related exposure falls below the threshold levels established in the Proposition. Proposition 65 does not otherwise restrict or prohibit the use of any listed chemical.

The Proposition required the list to include, at a minimum, substances identified by reference in the State's Labor Code. Three mechanisms are available for adding chemicals to the Proposition 65 list. These listing mechanisms provide a comprehensive approach to identify chemicals which may qualify for listing. One listing mechanism results from findings of the "state's qualified experts" (panels of scientists from outside of State government) following their consideration of evidence compiled and analyzed by the OEHHA scientists. The two other listing mechanisms are administrative in nature, and these are described in more detail below, followed by a status report of our progress in implementing them. As the lead agency for implementation of Proposition 65, OEHHA provides technical support for all three listing mechanisms. The list contains a wide range of substances, some of which are common and widely used, such as tobacco

smoke and aspirin, or occur as contaminants in commonly used products such as aflatoxin in peanut butter. Other listed chemicals, not widely recognizable by the general public, may result in exposures in the occupational environment.

Administrative Listing Mechanisms of Proposition 65

Under one administrative listing mechanism, a chemical may be added to the Proposition 65 list if another body, one considered to be an “authoritative body ” by the state’s qualified experts, has formally identified the chemical as causing cancer or reproductive toxicity. The regulations governing this administrative mechanism are set forth in Title 22, California Code of Regulations, Section 12306 (22 CCR § 12306). Under the other administrative listing mechanism, chemicals are listed under Proposition 65 if a state or federal agency has “formally required” that the chemical be labeled or identified as causing cancer or reproductive toxicity. The regulations governing this other administrative mechanism are set forth in 22 CCR § 12902.

OEHHA continually monitors the work products of the relevant bodies described above to identify chemicals, which may meet the regulatory criteria for listing under the administrative mechanisms (22 CCR §§ 12306 and 12902). Chemicals identified for possible administrative listing undergo careful review by OEHHA to determine whether these criteria have been met. Chemicals then undergo review by other agencies of California State government. Next, OEHHA notices in the *California Regulatory Notice Register* (CRNR) and on its web site the possible administrative listing of a set of chemicals. For each set of proposed administrative listings, a document detailing the basis for the possible listing is made available. In the case of an authoritative body listing, the document describes the scientific information relied on by the authoritative body that appears to meet the criteria specified in regulation, and names the harmful effect identified by that body. The public has a 60-day comment period, which includes a public forum, to provide comments on the information presented in the document and any additional information which is deemed relevant to the consideration of administrative listing. OEHHA responds directly to those who provide comments, as described below. If, after reviewing the comments submitted during the initial public comment period, OEHHA determines that the criteria for listing have been met, a Notice of Intent to List is published in the CRNR and posted on OEHHA’s web site, beginning a second public comment period, which lasts for 30 days. Following review of comments submitted during the second public comment period, OEHHA determines whether or not the criteria for administrative listing have been met, and if so, there is publication of a notice indicating the chemical has been added to the Proposition 65 list.

Following each public comment period, letters are sent to those who provide comments. These letters address the specific concerns raised in the comments submitted by that individual or firm, and discuss the rationale for OEHHA’s decision as to whether or not we will continue with the administrative listing of the chemical.

Listing by an administrative mechanism first occurred in 1987, and such listings have continued on a regular basis since then. Of the 689 listings under the Proposition to date, over half (359) of these have been made through an administrative listing mechanism, as noted in the table below.

Listing Procedure	Listings
Labor Code	57
Authoritative Bodies	197
Formally Required	162
State's Qualified Experts	273

Progress Report on Administrative Listing Activities

In June of 1998, OEHHA held a daylong workshop on the authoritative bodies listing mechanism, in response to interest on the part of the state's qualified experts, the regulated industry, and environmental organizations regarding the implementation of this provision of the Proposition. The event was well attended and very informative, with presentations made by representatives of many interested parties to a panel of OEHHA scientists and management, with some of the scientists who make up the state's qualified experts also in attendance.

This workshop was followed by separate meetings of the two Committees of the state's qualified experts which consider evidence for listing chemicals under Proposition 65 and have the authority to designate bodies as authoritative. At these meetings, the bodies designated as authoritative were reviewed and in some cases modified to address concerns that the body be clearly authoritative in the subject area and follow certain scientific procedures. For example, the National Toxicology Program (NTP) was removed from the list of bodies considered to be authoritative with respect to reproductive toxicity, and designation of the International Agency for Research on Cancer (IARC) was modified to be authoritative for reproductive toxicity only in the case of transplacental carcinogenesis. The remaining authoritative bodies for reproductive toxicity, the U.S. Environmental Protection Agency (U.S. EPA), the U.S. Food and Drug Administration (U.S. FDA) and the National Institute for Occupational Safety and Health (NIOSH) were retained. No changes were made to the list of bodies considered to be authoritative with respect to carcinogenicity, which is comprised of the U.S. EPA, U.S. FDA, IARC, NIOSH and NTP.

In 1996, OEHHA initiated a comprehensive retrospective review of all relevant work products generated by the bodies then designated as authoritative. Many candidate chemicals have now been listed, while several others are expected to complete the listing process during the next year. There

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are currently 51 administrative listing candidates that have entered at least one of the public comment phases of the listing process, but have not been added to the list or removed from consideration.

In addition to these, in 1997 OEHHA initiated a review of 65 chemicals identified by the U.S. EPA as causing reproductive toxicity. Of 286 chemicals added to the Toxic Release Inventory (TRI) in 1994, 65 that were added to this federal TRI list wholly or in part on the basis of reproductive toxicity became eligible for consideration under Proposition 65. Subsequently, several environmental groups sued to compel OEHHA to automatically list all of these chemicals under Proposition 65. Various agricultural industry groups counter-sued to prevent the listings altogether. The Sacramento Superior Court ruled in April 1998, that U.S. EPA TRI findings provided a basis for possible listing of chemicals under Proposition 65, and that OEHHA was proceeding appropriately in its chemical by chemical determination of whether the applicable Title 22 regulatory criteria had been met. A writ of mandate was issued by the Court in October 1998, which required OEHHA to make a final decision on at least 50 chemicals by June 30, 1999, and to make a final decision on the remaining TRI chemicals in a timely manner. To date, of these 65 TRI chemicals, 35 have been administratively listed under Proposition 65, 18 have been determined not to meet the listing criteria, and another 12 are still under consideration for possible listing.

As is standard procedure for the OEHHA process, letters have been sent to those who provided comments on possible administrative listing of TRI or other chemicals, addressing the specific concerns raised in the comments submitted by that individual or firm, and discussing the rationale for OEHHA's decision as to whether or not the administrative listing process for that chemical would continue. Because of the keen public interest shown in the possible listing of TRI chemicals, for each of the TRI chemicals determined not to meet the listing criteria (18 to date), the basis for that determination has been provided in documents posted on OEHHA's website.

For other chemicals, you may call the Proposition 65 Implementation Office at (916) 445-6900 to request further relevant information regarding those chemicals subject to the administrative listing process.

Sincerely,

Joan E. Denton, Ph.D.
Director